

### **REMARKS**

Claims 12-17, 19, 23 and 24 are now currently pending in the present application. New claim 24 has been added, which finds support in the specification, at least, at page 7, lines 16-18. Claims 12-17 and 19 have been amended to correct matters of form and clarity. No new matter has been added by way of the present claim amendments.

#### ***Rejection under 35 U.S.C. §112, first paragraph***

##### **Written Description**

The Examiner has rejected claims 12-17, 19 and 23, as lacking written description in the specification. Applicants respectfully traverse.

The description of the present application describes, at page 4, lines 18-28, that amino acids used in the peptide conjugates according to the invention can be in D, L or DL form, so that these peptide conjugates can have at least asymmetric carbon atom. As a result, the peptide conjugates according to the invention can exist in the form of enantiomers, diastereoisomers, or mixtures thereof.

Indeed, the existence of optical isomers, either enantiomers or diastereoisomers, depend on the presence of at least one asymmetric carbon atom. Most amino acids can exist as two distinct optical isomers called D and L. When both D and L isomers are used, it is said that the amino acids used is in DL form. **See the Wikipedia article on amino acids, paragraph entitled "Isomerism" on page 3, which is being submitted herewith for the Examiner's consideration.**

Enantiomers and diastereoisomers are optical isomers which are named based upon whether they are mirror images of each other. **See Wikipedia articles on Enantiomers and Diastereoisomers.**

As a result, when synthesizing the peptide conjugates according to the present invention, one of ordinary skill in the art would know how to obtain an enantiomer, a diastereoisomer or mixtures thereof, of particular peptide conjugates by using for each amino acid either the D, L or DL form.

The objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)(emphasis added). MPEP § 2163.02

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

The presently claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention. The knowledge and level of skill in the present field of endeavor would permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

#### Enablement

Claims 12-17, 19 and 23 stand rejected as being broader than enabled by the specification.

Claim 12 has been amended to delete the phrase "preventative and curative". Moreover, Applicants submit that the results displayed in the present application on the growth of mouse

vibrissae demonstrate that the peptide conjugates according to the invention have an activity on hair growth. As evidence supporting the enablement of the present invention, Applicants submit herewith a **Declaration Under Rule 1.132** which demonstrates:

1. that the peptide conjugates according to the present invention alone have an *inducing activity* on human hair growth *in vitro*, which is at least comparable to the activity of minoxidil, a reference compound improving hair regrowth (*See Annex 1*); and
2. a clinical study on healthy volunteers of the *anti-hair loss activity* of a peptide conjugate according to the present invention (*See Annex 2*).

Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

***Rejection under 35 U.S.C. §112, second paragraph***

Claims 12-17, 19 and 23 stand rejected as being indefinite.

Specifically, the Examiner has rejected claim 12 because the Examiner finds the phrase “effective amount” unclear. In response, Applicants have amended claim 12 to recite “a therapeutically effective amount.” Applicants respectfully submit that this language is sufficient to overcome the outstanding rejection. Applicants have also added a new claim to recite the concentration of the peptide conjugate in accordance with the specification at page 7, lines 16-18.

Claim 12 has additionally been amended to overcome the outstanding rejections found at paragraphs 2 and 3 on page 7 of the Office Action. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections.

***Claim Observations***

The claims have been amended to correct the matters of form noted by the Examiner’s claim observations found on page 7 of the Office Action.

In view of the foregoing, Applicants believe the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: December 19, 2007

Respectfully submitted,

By 

Andrew D. Meikle

Registration No.: 32,868

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachments: **Wikipedia article on amino acids, paragraph entitled  
"Isomerism"**  
**Wikipedia articles on Enantiomers and Diastereoisomers**  
**Declaration Under Rule 1.132**